K131664

DEC 18 2013

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92

1. APPLICANT

White Peaks Dental Systems GmbH & Co. KG
Langeheide 9
45239 Essen
Germany

PHONE: 49 281 206458-0
FAX: 49 281 206458-13
EMAIL: info@white-peaks-dental.com
Date Prepared: June 12, 2013

2. SUBMITTER and CONTACT

John P. Waters
Consultant
Whip Mix Corporation
361 Farmington Avenue
Louisville, KY 40217

PHONE: 502-634-5357
FAX: 502-634-4512
EMAIL: jwaters@whipmix.com

3. DEVICE NAME

Copra Temp

4. COMMON OR USUAL NAME AND CLASSIFICATION

Temporary Crown and Bridge Resin
Regulation Number: 872.3770
Product Code: EBG
Classification: Class II

5. PREDICATE DEVICE INFORMATION

Zeno PMMA Disc **(K080182)**
BRIGHTGLASS Discs **(K122025)**

6. DEVICE DESCRIPTION

White Peaks Copra Temp is a device made from high quality 100% PMMA (polymethylmethacrylate) and is intended for use in the oral cavity for up to six (6) months while awaiting a permanent restoration. Two (2) pontics are allowed between two (2) abutment teeth. Restorations are designed using CAD technology and uses scans or models for the basis of the restoration to be milled. Copra Temp Blanks are available in a variety of thicknesses for different milling systems and are also available in a variety of Vita shades.

7. INDICATIONS FOR USE STATEMENT

White Peaks Copra Temp is a device made from PMMA (polymethylmethacrylate) for the fabrication of temporary crowns and bridges and is intended for use in the oral cavity for up to six (6) months while awaiting a permanent restoration. Restorations are designed and manufactured by a dental Professional (Technician) using CAD technology.

8. SUBSTANTIAL EQUIVALENCE WITH PREDICATE DEVICES

(new) White Peaks Copra Temp	BRIGHTGLASS	ZENO PMMA
Class II Device	Class II device	Class II device
510(k) Pending	510(k) 122025	510(k) 080182
PMMA	PMMA	PMMA
Various Vita Shades	Various Vita Shades	Two (2) Vita Shades
Variable Thickness Milling Blank	Variable Thickness Milling Blank	Milling Blank in two (2) thicknesses
Machined using any milling system	Machined in all appropriate CAM Milling Centers	Machined in all machines of the ZENO Tech system
Flexural Strength 113 MPA	Flexural Strength 106 MPA	Flexural Strength 105 MPA

9. SAFETY AND EFFECTIVNESS

PMMA has a well-documented history for use in medical device applications and has been in use for many years. Based on the similarities in materials, descriptions, use, and device characteristics we believe our Copra Temp device is substantially equivalent to the predicates.

10. PRE-CLINICAL TESTING AND STANDARDS USED

Pre-clinical testing was performed to determine the physical properties of Copra Temp and for Biocompatibility and the tests passed per the requirements of ISO:10477, ISO:10993-1, ISO: 10993-3, ISO: 10993-5 and ISO:10993-10.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 18, 2013

White Peaks Dental Systems GmbH & Company KG
C/O Mr. John P. Waters
Consultant
Whip Mix Corporation
361 Farmington Avenue
LOUISVILLE KY 40217

Re: K131664
Trade/Device Name: COPRA TEMP
Regulation Number: 21 CFR 872.3770
Regulation Name: Temporary Crown and Bridge Resin
Regulatory Class: II
Product Code: EBG
Dated: September 18, 2013
Received: September 27, 2013

Dear Mr. Waters:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer-S for

Erin Keith, M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN) K131664

DEVICE NAME: **COPRA TEMP**

INDICATIONS FOR USE:

White Peaks Copra Temp is a device made from PMMA (polymethylmethacrylate) for the fabrication of temporary crowns and bridges and is intended for use in the oral cavity for up to six (6) months while awaiting a permanent restoration. Restorations are designed and manufactured by a dental Professional (Technician) using CAD technology.

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: X OR Over-The-Counter Use:

Susan Runner DDS MA

Mary S. Runner -S
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